United States Environmental Protection Agency
Region 5

IN THE MATTER OF:	)	
	)	
3M Company Specialty Materials Manufacturing Division Cordova, Illinois	)	**FINDING OF VIOLATION**
	)	**EPA-5-03-IL-22**
Proceedings Pursuant to the Clean Air Act, 42 U.S.C. §§ 7401 et seq.	)	

FINDING OF VIOLATION

The United States Environmental Protection Agency (U.S. EPA) finds that 3M Company is violating Section 112 of the Clean Air Act, 42 U.S.C. § 7412. Specifically, 3M Company is violating the National Emissions Standards for Hazardous Air Pollutants (NESHAP) for Pharmaceutical Production at 40 C.F.R. Part 63, Subpart GGG as follows:

Regulatory Authority

1. The NESHAP for Pharmaceutical Production defines an affected source as a source that: a) manufactures a pharmaceutical product; b) is located at a plant site that is a major source as defined in Section 112(a) of the Clean Air Act (CAA) and; c) processes, uses, or produces Hazardous Air Pollutants (HAPs).

2. The NESHAP for Pharmaceutical Production was proposed on April 2, 1997 and became final on September 21, 1998. The owner or operator of an existing affected source must comply with the provisions of this subpart no later than October 21, 2002. 40 C.F.R. § 63.1250(f)(1)

3. The NESHAP, at 40 C.F.R. § 63.6(e)(3)(i), requires the owner or operator of an affected source to develop and implement a written startup, shutdown, and malfunction plan (SSMP)that describes, in detail, procedures for operating and maintaining the source during periods of startup, shutdown, and malfunction and a program of corrective action for malfunctioning process and air pollution control equipment used to comply with the relevant standard.

4. The NESHAP, at 40 C.F.R. § 63.1259(a), requires the owner or operator of an affected source to comply with the recordkeeping requirements in Subpart A of this part.

5. The NESHAP, at 40 C.F.R. § 63.1259(a)(3), requires the owner or operator of an affected source to develop and implement a written SSMP and keep the current and superceded versions of this plan onsite.

6. The NESHAP, at 40 C.F.R. § 63.1260(i)(1), requires an owner or operator of an affected source who has taken action consistent with procedures specified in the source's SSMP to submit a report on the same schedule as the periodic reports.

7. The NESHAP, at 40 C.F.R. § 63.1260(i)(2), requires an owner or operator who has taken action not consistent with the procedures specified in the affected source's SSMP to submit an immediate SSMP.

8. The NESHAP, at 40 C.F.R. § 63.1256(a)(4), requires an owner or operator of a source subject to this subpart to comply with the requirements of this section for maintenance wastewater containing partially soluble or soluble HAP.

9. The NESHAP, at 40 C.F.R. § 63.1256(a)(4)(i), requires that an owner or operator prepare a description of maintenance procedures for management of wastewater generated from the emptying and purging of equipment in the process during temporary shutdowns for inspections, maintenance, and repair and during periods which are not shutdowns.

10. The NESHAP, at 40 C.F.R. § 63.10(b)(3), requires the owner or operator of a stationary source that emits (or has the potential to emit, without considering controls) one or more HAPs and is not subject to a relevant standard or other requirements established under this part, to keep a record of the applicability determination on site for a period of five years after the determination. The analysis shall be sufficiently detailed to allow the Administrator to make a finding about the source's applicability status with regard to the relevant standard or other requirements.

11. The NESHAP, at 40 C.F.R. § 63.1259(a)(2), requires the owner or operator of a stationary source that is not subject to this subpart to keep a record of the applicability determinations as specified in § 63.10(b)(3).

12. The NESHAP, at 40 C.F.R. § 63.1260(f)(1), requires the owner

or operator to submit the results of any applicability determinations, emission calculations or analyses used to identify and quantify HAP emissions from the affected source in the Notification of Compliance Status Report (NOCSR).

13. The NESHAP, at 40 C.F.R. § 63.1251, requires the owner or operator to generate operating scenarios as defined in this section.

14. The NESHAP, at 40 C.F.R. § 63.1259(b)(8), requires the owner or operator to keep records up-to-date and a readily accessible schedule or, log of each operating scenario updated daily or, at a minimum, each time a different operating scenario is put into operation.

15. The NESHAP, at 40 C.F.R. § 63.1259(c), requires the owner or operator of an affected source to keep records of each operating scenario which demonstrates compliance with this subpart.

16. The NESHAP, at 40 C.F.R. § 63.1260(f)(4), requires the owner or operator to submit in the NOCSR a listing of all operating scenarios.

17. The NESHAP, at 40 C.F.R. § 63.1253(a), provides that an owner or operator of a storage tank meeting the criteria of paragraph (a)(1) of this section is subject to the requirements of paragraph (b) of this section. The owner or operator of a storage tank meeting the criteria of paragraph (a)(2) of this section is subject to the requirements of paragraph (c) of this section.

18. The NESHAP, at 40 C.F.R. § 63.1257(d)(3)(iii)(B), requires the owner or operator to demonstrate that the condenser, during periods when the condenser is operating as a process condenser, is properly operated if the process condenser meets either of the criteria described in paragraphs(d)(3)(iii)(B)(1) and (2) of this section.

19. The NESHAP, at 40 C.F.R. § 63.1260(f)(3), requires the owner or operator to submit in the NOCSR descriptions of monitoring devices, monitoring frequencies, and the values of monitored parameters established during the initial compliance demonstrations, including data and calculations to support the levels established.

20. The NESHAP, at 40 C.F.R. § 63.1257(d)(3)(iii)(A), requires an owner or operator, during periods in which a condenser functions as an air pollution control device, to calculate controlled

emissions using the emission estimation equations.

21. The NESHAP, at 40 C.F.R. § 63.1258(a), requires an owner or operator to provide evidence of continued compliance with the standard as specified in this section. During the initial compliance demonstration, maximum or minimum operating parameter levels, as appropriate, shall be established for emission sources that will indicate the source is in compliance.

22. The NESHAP, at 40 C.F.R. § 63.1258(b)(1), requires an owner or operator of each control device to install and operate monitoring devices and operate within the established parameter levels to ensure continued compliance with the standard.

23. The NESHAP, at 40 C.F.R. § 63.1258(b)(1)(i), requires an owner or operator of control devices that control vent stream emissions totaling less than 1 ton per year HAP emissions, before control, to conduct monitoring consisting of daily verification that the devices are operating properly.

24. The NESHAP, at 40 C.F.R. § 63.1258(b)(1)(iii), requires an owner or operator of each condenser to establish the maximum condenser outlet gas temperature as a site-specific operating parameter which must be measured and recorded at least every 15 minutes during periods in which the condenser is functioning in achieving the HAP removal required by this subpart.

25. The NESHAP, at 40 C.F.R. § 63.1258(b)(3)(i), requires an owner or operator of devices controlling less than 10 tons per year of HAP for which a performance test is not required to set parametric levels based on the design evaluation.

26. The NESHAP, at 40 C.F.R. § 63.1258(b)(3)(ii), requires an owner or operator of devices controlling greater than 10 tons per year of HAP for which a performance test is not required to set parametric levels based on the methods of this section.

27. The NESHAP, at 40 C.F.R. § 63.1260(f)(5), requires an owner or operator to submit in the NOCSR the descriptions of worst-case operating and/or testing conditions for control devices.

28. The NESHAP, at 40 C.F.R. § 63.1257(a)(1), requires the owner or operator of a control device to address the composition and organic HAP concentration of the vent stream entering the control device in a design evaluation.

29. The NESHAP, at 40 C.F.R. § 63.1257(a)(1)(iii), requires the owner or operator of a condenser to consider the vent stream flow

rate, relative humidity, and temperature in the design evaluation so that the design outlet organic HAP compound concentration level, design average temperature of the condenser exhaust vent stream, and the design average temperatures of the coolant fluid at the condenser inlet and outlet are established. The temperature of the gas stream exiting the condenser must be measured and used to establish the outlet organic HAP concentration.

30. The NESHAP, at 40 C.F.R. § 63.1260(f)(2), requires the owner or operator to submit in the NOCSR the results of emission profiles, performance tests, engineering analyses, design evaluations, or calculations used to demonstrate compliance.

31. The NESHAP, at 40 C.F.R. § 63.1256(a), requires the owner or operator of any affected source to comply with the general wastewater requirements in paragraph (a)(1) through (3) of this section and the maintenance wastewater provisions in paragraph (a)(4) of this section.

32. The NESHAP, at 40 C.F.R. § 63.1256(a)(1), requires the owner or operator to identify, for each point of determination (POD), wastewater streams meeting the criteria specified in paragraphs (a)(1)(i)(A) through (C) of this section.

33. The NESHAP, at 40 C.F.R. § 63.1257(d)(2)(i), provides that an owner or operator shall determine uncontrolled emissions of HAP using measurements and/or calculations for each batch emission within each unit operation according to the engineering evaluation methodology in paragraphs (d)(2)(i)(A) through (H) of this section.

34. The NESHAP, at 40 C.F.R. § 63.1257(d)(2)(i)(C), requires an owner or operator to calculate emissions caused by the heating of a vessel.

35. The NESHAP, at 40 C.F.R. § 63.4(a)(1), provides that no owner or operator subject to the provisions of this part shall operate any affected source in violation of this requirement of this part except under an extension of compliance granted by the Administrator, State with an approved permit program, or by the President under Section 112(i)(4).

Factual Background

36. 3M Company owns and operates a chemical plant at 22614 Route 84 North in Cordova, Illinois 61242.

37. 3M Company is subject to the requirements at 40 C.F.R. Part 63 Subpart GGG.

38. 3M Company has two "burden centers" which are subject to the Pharmaceutical MACT, BC-34 and BC-3A.

39. 3M Company submitted an incomplete NOCSR on March 20, 2003 to U.S. EPA.

40. During the June 2-3, 2003 U.S. EPA inspection, the U.S. EPA inspectors observed that the NOCSR remained incomplete.

41. In the April 19, 2002 Pre-Compliance Report (PCR) and in the NOCSR, 3M Company identified all of its condensers as process condensers and reported not having any control devices.

42. 3M Company has not performed an initial compliance demonstration for its process condensers.

43. 3M Company developed and implemented a Startup/Shutdown/Malfunction Plan (SSMP) on March 20, 2003.

44. 3M Company developed and implemented a Maintenance Wastewater Plan on May 30, 2003, which appeared as part of the amended SSMP on site.

45. During the June 2-3, 2003 U.S. EPA inspection, 3M Company did not have applicability determinations available for the U.S. EPA.

46. In the PCR and the NOCSR, 3M Company identified no wastewater streams generated from its Pharmaceutical Manufacturing Process Units (PMPUs).

47. 3M Company has two storage tanks, Tank 13 (Commercial Heptane) and Tank 39 (Methanol), that are used in the manufacturing of the Pharmaceutical MACT-affected processes.

48. An emission model for one of the Pharmaceutical-MACT processes reviewed during the June 2-3, 2003 U.S. EPA inspection did not match the batch recipe for the process and omitted a series of steps from the cleaning and the manufacturing parts of the process.

49. During the June 2-3, 2003 U.S. EPA inspection, 3M stated that no design evaluations were performed for the condensers or other control devices subject to the Pharmaceutical MACT.

Violations: Reporting and Recordkeeping

50. 3M Company failed to have an SSMP developed and implemented by the compliance date of October 21, 2002. This is a violation of 40 C.F.R. § 63.6(e)(3)(i), 40 C.F.R. § 63.1259(a), 40 C.F.R. § 63.1259(a)(3), 40 C.F.R. § 63.1260(i)(1), and 40 C.F.R. § 63.1260(i)(2).

51. 3M Company failed to have a Maintenance Wastewater Plan developed and implemented by the compliance date of October 21, 2002. This is a violation of 40 C.F.R. § 63.1256(a)(4) and 40 C.F.R. § 63.1256(a)(4)(i).

52. 3M Company failed to have Applicability Determinations on site available for the U.S. EPA to make a finding about the source's applicability status with regards to the relevant standard or other requirement. This is a violation of 40 C.F.R. § 63.10(b)(3), 40 C.F.R. § 63.1259(a)(2), and 40 C.F.R. § 63.1260(f)(1).

53. 3M Company has not completed operating scenarios or a log of operating scenarios to meet the definition in 40 C.F.R. § 63.1251 with regard to the relevant standard. This is a violation of 63.1251 (Definition of Operating Scenarios), 40 C.F.R. § 63.1259(b)(8), 40 C.F.R. § 63.1259(c), and 40 C.F.R. § 63.1260(f)(4).

Violations: Storage Tanks

54. 3M Company has not classified the two storage tanks, Tank 13 and Tank 39, that are used for pharmaceutical production, as part of any Pharmaceutical Manufacturing Process Unit. This is a violation of 40 C.F.R. § 63.1253(a).

Violations: Condensers/Control Devices

55. 3M Company has not performed an initial compliance demonstration for its process condensers. This is a violation of 40 C.F.R. § 63.1257(d)(3)(iii)(B) and 40 C.F.R. § 63.1260(f)(3).

56. 3M Company has not identified any control devices associated with the Pharmaceutical MACT processes. This is a violation of 40 C.F.R. § 63.1257(d)(3)(iii)(A),, 40 C.F.R. § 63.1258(a), 40 C.F.R. § 63.1258(b)(1), 40 C.F.R. § 63.1258(b)(1)(i), 40 C.F.R. § 63.1258(b)(1)(iii), 40 C.F.R. § 63.1258(b)(3)(i), 40 C.F.R. § 63.1258(b)(3)(ii), and 40 C.F.R. § 63.1260(f)(5).

57. 3M Company has not performed any design evaluations on the

control devices used for Pharmaceutical MACT processes. This is a violation of 40 C.F.R. § 63.1257(a)(1), 40 C.F.R. § 63.1257(a)(1)(iii), and 40 C.F.R. § 63.1260(f)(2).

Violations: Wastewater

58. 3M Company failed to identify wastewater streams generated from the Pharmaceutical MACT processes. This is a violation of 40 C.F.R. § 63.1256(a) and 40 C.F.R. § 63.1256(a)(1).

Violations: Emission Calculation

59. 3M Company has modeled the Pharmaceutical MACT process, Cordran, incorrectly in its emission model software. This is a violation of 40 C.F.R. § 63.1257(d)(2)(i) and 40 C.F.R. § 63.1257(d)(2)(i)(C).

Violation: General

60. 3M Company operated an affected source in violation of the Pharma-MACT, 40 C.F.R. Part 63 Subpart GGG. This is a violation of 40 C.F.R. § 63.4(a)(1).

8/12/2003
Date

Cheryl L. Newton, Acting Director
Air and Radiation Division

CERTIFICATE OF MAILING

I, Shanee Rucker, certify that I sent a Finding of Violation, No. EPA-5-03-IL-22, by Certified Mail, Return Receipt Requested, to:

Ken Ramm, Environmental, Health, Safety
and Regulatory Manager
3M Company Specialty Materials Manufacturing Division
22614 Route 84 North
Cordova, Illinois 61242

I also certify that I sent copies of the Finding of Violation by first class mail to:

Julie Armitage, Section Manager
Compliance and Systems Management Section
Illinois Environmental Protection Agency
P.O. Box 19506
Springfield, Illinois 62794-9506

Mike Knobloch, District Engineer
Illinois Environmental Protection Agency
1630 - 5th Avenue
Moline, Illinois 61265

on the 13th day of August, 2003.

Loretta Maffei for
Shanee Rucker,
Administrative Program Assistant
AECAS, (MI/WI)
(312) 886-6086

CERTIFIED MAIL RECEIPT NUMBER: 7001 0320 0006 1467 1572